

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: ETHICON WAVE I CASES LISTED IN EXHIBIT A TO PLAINTIFFS' MOTION	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE
CERTAIN TESTIMONY OF JULIE DROLET, M.D.**

INTRODUCTION

Dr. Drolet is a gynecologist with board certifications in Female Pelvic Medicine and Reconstructive Surgery and Obstetrics and Gynecology. Julie Drolet, MD, Expert Report (Feb. 29, 2016) ("Drolet Report") [Dkt. 2093-2]. She is without question a bona fide expert in the fields of pelvic medicine generally and in the surgical treatment of pelvic organ prolapse and stress urinary incontinence specifically.

Dr. Drolet has issued a combined report covering both general and case-specific topics for one of the Wave I cases – *Rose Gomez v. Ethicon, Inc.* Civ. A. No. 2:12-cv-344. Plaintiff has not challenged any of Dr. Drolet's case-specific opinions. Likewise, Plaintiff has not challenged the overwhelming majority of Dr. Drolet's general opinions.

Plaintiff's motion seeks to limit Dr. Drolet's testimony on only eight points: (1) Plaintiff contends that Dr. Drolet's discussion about pelvic organ prolapse, stress urinary incontinence,

and the various treatment options constitute inadmissible narrative testimony; (2) Plaintiff claims that Dr. Drolet's opinions regarding the risk profiles of TVT-O and Prolift+M are unsupported; (3) Plaintiff argues that Dr. Drolet is not competent to testify regarding the general state of medical knowledge regarding the risks associated with pelvic floor surgery; (4) Plaintiff argues that Dr. Drolet is impermissibly attempting to opine regarding the intent of the medical device industry, Ethicon, and the FDA; (5) Plaintiff contends that Dr. Drolet is unqualified to opine regarding the significance of the FDA 510(k) clearance of TVT-O and Prolift+M; (6) Plaintiff claims that Dr. Drolet's opinions regarding the subject instructions for use are unreliable; (7) Plaintiff argues that Dr. Drolet seeks to offer improper legal conclusions; and (8) Plaintiff avers that Dr. Drolet was unable to identify the documents that she relied upon in arriving at her opinions. None of these arguments has any merit.

First, Dr. Drolet's discussion of pelvic organ prolapse, stress urinary incontinence, and the treatment options for same is not impermissible narrative testimony. Rather, the discussion of these medical conditions and treatment options informs the basis of Dr. Drolet's opinion regarding the propriety of TVT-O and Prolift+M as surgical options.

Second, Dr. Drolet fully supports her opinions regarding the risks and benefits of TVT-O and Prolift +M through her research and clinical experience with these products. Plaintiff's desire to confront Dr. Drolet with documents that purportedly contradict her opinions goes to the weight, not admissibility, of her opinion testimony.

Third, Dr. Drolet is fully competent to discuss the general state of medical knowledge regarding the risks of pelvic floor surgery. Plaintiff attempts to categorize Dr. Drolet's opinions about the general state of medical knowledge as impermissible "mind reading." *See* Drolet (3/31/16) Dep. Tr. [Dkt. 2093-4] at 65:10-65:13. But Dr. Drolet, a licensed, trained, and board-

certified physician, is fully competent to opine regarding the state of medical knowledge and the standard of care owed by pelvic surgeons, both of which are relevant to Ethicon's learned intermediary defense to Plaintiff's failure to warn claim.

Fourth, Dr. Drolet makes no attempt to opine regarding the intent of the medical device industry, or Ethicon, or the FDA as alleged by Plaintiff. This argument is a red herring.

Fifth, Dr. Drolet does not intend to opine of the significance of the FDA 510(k) clearance process. In her deposition, Plaintiff asked Dr. Drolet questions regarding the clearance, and she answered those questions. Provided that Plaintiff does not open the door, Dr. Drolet does not intend to offer this opinion. To the extent Plaintiff opens the door, Dr. Drolet should be entitled to respond.

Sixth, Dr. Drolet's experience as a pelvic floor surgeon makes her uniquely qualified to opine regarding the adequacy of the products' IFUs.

Seventh, Dr. Drolet makes no improper legal conclusions. This too is a red herring.

Eighth, Dr. Drolet fully identified the documents upon which she relied in arriving at her opinions. If there were documents in her possession which she did not review or documents available to her that she did not request, that goes to the weight, not admissibility, of her opinion testimony.

For these reasons, Plaintiff's motion to limit Dr. Drolet's testimony should be denied.

I. ARGUMENT

A. Dr. Drolet's Opinion Testimony Regarding POP, SUI, and the Various Treatment Options Serve as the Bases For Her Other Opinions

Plaintiff argues that Dr. Drolet's opinion testimony regarding POP, SUI, and the treatment options for same constitute impermissible narrative testimony. Pls.' Br. [Dkt. 2094] at 2-3. Contrary to Plaintiff's assertion, Dr. Drolet's opinions on these points serve, in part, as the bases

for her opinions regarding the safety, efficacy, and risk/benefit analysis regarding the use of Prolift+M and TVT-O.

As this Court has held, “experts may form opinions by relying on facts that they have ‘been made aware of,’ as long as ‘experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject.’” *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 646 (S.D. W. Va. June 4, 2013) (quoting Fed. R. Civ. P. 703). Additionally, this Court has held that “to the extent that [factual narratives] may present the bases for their expert opinions in this case” such factual narratives are admissible. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589 at 646; *Wise v. C.R. Bard, Inc.*, 2015 WL 521202, at *18–19 (S.D. W. Va. Feb. 7, 2015). Experts are not only entitled to explain the basis for their opinions, but the Federal Rules of Civil Procedure require that they do so. *See* Fed. R. Civ. P. 26(a)(2)(B) (expert’s “report must contain . . . a complete statement of all opinions the witness will express and the basis and reasons for them . . .”).

Dr. Drolet’s ultimate opinion in this case is that “the Posterior Prolift +M and TVT-O were appropriate and effective options for [Plaintiff].” Drolet Report [Dkt. 2093-2] at 49. To arrive at this opinion, Dr. Drolet must have an appreciation and understanding for Plaintiff’s medical conditions – POP and SUI. Dr. Drolet must know and understand the alternative surgical options. She must understand the risks and benefits of the other surgical options. She must understand the risks and benefits of the Prolift+M and the TVT-O. Only after consideration of all of these things can she arrive at the opinion of the appropriateness and effectiveness of Prolift+M and TVT-O surgeries in Plaintiff.

Additionally, Dr. Drolet’s discussions of POP, SUI, and the treatment options include specific citations to studies, articles, and authorities that pelvic surgeons, like Dr. Drolet, review

and rely upon in their medical practice and treatment of their patients. Drolet Report [Dkt. 2093-2] at 5-30.

Plaintiff's other objection regarding this testimony is that there may exist other studies or articles not cited by Dr. Drolet, which allegedly contradict the studies cited by Dr. Drolet. *See* Pls.' Br. [Dkt. 2094] at 2. This argument does not go to the admissibility of Dr. Drolet's testimony; rather, this is an issue for cross-examination. Neither the law nor the rules of evidence or civil procedure require an expert witness to review each and every study, article, and paper published on a given topic or to explain why an expert has elected not to rely upon a certain study, article, or paper. Plaintiff is certainly entitled to question Dr. Drolet regarding the documents upon which she relied and her reasons for not relying on others. But this is a question for cross-examination, not for exclusion under *Daubert*.

Plaintiff also makes a passing objection to the fact that Dr. Drolet "does not offer an opinion regarding the complication or efficacy rates associated with the Prolift+M or TVT-O products." Pls.' Br. [Dkt. 2094] at 2. Plaintiff argues that in the absence of such an opinion Dr. Drolet's other opinions are "unhelpful." *Id.* As an initial matter, it should be noted that Plaintiff cites nothing for the proposition that in the absence of an opinion regarding complication and efficacy rates, an expert's opinion is deemed unreliable. More importantly though, Dr. Drolet throughout her report discusses her extensive review of medical literature, including Level 1 evidence such as Cochrane Review meta-analyses assessing thousands of patients, and numerous randomized controlled trials, including medical literature addressing the complication and efficacy rates observed. not to mention public statements by medical societies in the fields of urology. *See* Drolet Report [Dkt. 2093-2] at 10-12, 18-24. It is unclear from Plaintiff's brief what

more she contends Dr. Drolet allegedly should have done to render her opinion testimony “helpful.”

Dr. Drolet’s discussion of POP, SUI, and the various treatment options for these conditions form, in part, the bases of her opinions. These discussions do not constitute impermissible narrative testimony and are admissible.

B. Dr. Drolet’s Opinions Regarding the Risk/Benefit Profile of TVT-O And Prolift+M Are Sufficiently Based Upon Her Knowledge of the Medical Literature And Her Clinical Experience With the Products

Plaintiffs contend that Dr. Drolet did not “disclose[] a reliable basis” for her conclusion that “[t]he benefits of Prolift+M and TVT-O outweighed the risks.” Pls.’ Br. [Dkt. 2094] at 3 (quoting Drolet Report [Dkt. 2093-2] at 27). Plaintiffs’ argument in this regard is nonsensical. The challenged statement from Dr. Drolet appears on Page 27 of her report. Pages 2 thru 26 – the portion of her report that Plaintiff attacks as impermissible “narrative” testimony – is the basis for her risk/benefit opinion. For more than 25 pages, Dr. Drolet explains the medical conditions of POP and SUI, the risks and benefits of non-surgical treatments, the risks and benefits of non-mesh surgical treatments, and the risks and benefits of both mesh surgical treatments in general and Prolift+M and TVT-O surgical treatments specifically. *See* Drolet Report [Dkt. 2093-2] at 2-26. Throughout these explanations, Dr. Drolet cites to the medical literature, the professional organization position statements, her education, her training, and her clinical practice, all of which support and form the reliable bases upon which her opinion is based.

As part of this argument, Plaintiff contends that Dr. Drolet’s opinion – that the benefits outweigh the risk – is somehow contrary to the 2011 American College of Obstetrician and Gynecology (“ACOG”) 2011 committee opinion and that this alleged contradiction renders Dr. Drolet’s opinion unreliable. This purported conflict between Dr. Drolet’s opinion testimony and ACOG’s committee opinion, again, is not a question of the reliability of Dr. Drolet’s opinion. It

is a question that goes to the weight of her opinion testimony to be addressed on cross-examination.

The bulk of Plaintiff's argument regarding the reliability of Dr. Drolet's risk/benefit opinion focuses on Dr. Drolet's testimony that she was "unaware of any clinical benefits associated with Prolift+M as compared to Prolift." Pls.' Br. [Dkt. 2094] at 4 (emphasis added). Plaintiff's argument is premised on a nonsequitor: that Dr. Drolet must espouse a clinical benefit of Prolift+M as compared to Prolift in order to find that Prolift+M's benefits outweighed its risks. The Prolift+M and Prolift may have identical benefit-profiles and simultaneously the benefits of Prolift+M can still outweigh its risks. Plaintiff's objection along this line is premised on nothing more than a logical fallacy.

C. Dr. Drolet Is Well Qualified To Opine Regarding the General State of Medical Knowledge

Plaintiff argues that Dr. Drolet should not be allowed to opine that complications associated with Prolift+M and TVT-O were "well known" at the time when Plaintiff was implanted with her TVT-O and Prolift+M. Pls.' Br. [Dkt. 2094] at 5. Dr. Drolet is a board certified pelvic reconstruction surgeon with more than 20 years of clinical experience. Drolet Report [Dkt. 2094] at 1. She is, without question, a bona fide expert in the field of pelvic floor surgery.

Plaintiff's argument that Dr. Drolet should be prohibited from opining on the state of medical knowledge stems first from a misstatement of her opinion testimony. Plaintiff alleges that Dr. Drolet seeks to opine what risks are known by "all' physicians." Pls.' Br. [Dkt. 2094] at 5 (emphasis added). Nowhere in her report does Dr. Drolet attempt to say what "is" known by "all" physicians. She never attempts to impute knowledge to any individual surgeon or any class of surgeons.

Rather, Dr. Drolet provides descriptions of the complications associated with the devices. She supports those descriptions with published medical literature. Dr. Drolet opines that these complications are well known within the general state of knowledge in the medical community. Further, Dr. Drolet opines that the reasonably prudent pelvic floor surgeon would apprise herself of this general medical knowledge. For example, Plaintiff complains about Dr. Drolet's statement that "[a] reasonably prudent pelvic floor surgeon performing incontinence and prolapse surgeries would have already been aware of the potential for these complications." *See* Pls.' Br. [Dkt. 2094] at 5 (quoting Drolet Report at 18). This is an opinion regarding the standard of care for pelvic floor surgeons and the state of knowledge within the medical community.

Under Pennsylvania law,¹ the duty to warn for a pharmaceutical or medical device flows to the prescribing physician, not the patient. *Rowland v. Novartis Pharms. Corp.*, 34 F. Supp. 3d 556, 570 (W.D. Pa. 2014) (quoting *Daniel v. Wyeth Pharms., Inc.*, 15 A.3d 909, 924 (Pa. Super. Ct. 2011)); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 502 n.44 (W.D. Pa. 2012) (citing and quoting *Rosci v. AcroMed, Inc.*, 669 A.2d 959, 969 (Pa. Super. Ct. 1995)). Pennsylvania recognizes that it is the duty of the physician to know the characteristics of the products that he prescribes. *Rowland*, 34 F. Supp. 3d at 570 (quoting *Daniel*, 15 A.3d at 924). "[I]t is for the prescribing physician to use his independent medical judgment, taking into account the data supplied to him from the manufacturer, other medical literature, and any other sources available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug." *Id.* (emphasis added). Accordingly, under Pennsylvania law, physicians have an affirmative duty to know the characteristics of the medical devices that they use and to be apprised of the medical literature regarding those devices.

¹ Plaintiff Gomez is a resident of Pennsylvania, and her surgery was performed in Pennsylvania.

Dr. Drolet's opinion testimony regarding what was known by the medical community at the time of Plaintiff's surgery is directly relevant to Ethicon's learned intermediary defense to Plaintiff's failure to warn claim. Moreover, as a practicing, board certified surgeon, Dr. Drolet is amply qualified to opine regarding the state of medical knowledge.

D. Dr. Drolet Does Not Seek To Opine Regarding the Intent of the Medical Device Industry, Ethicon, Or the FDA

Plaintiff points to only four instances of Dr. Drolet allegedly attempting to opine on the intent of the industry, Ethicon, or the FDA:

- "The introduction of mesh in the treatment of [POP] was intended to attain an important goal of surgeons – improve the longevity of the repair." Pls.' Br. [Dkt. 2094] at 6.
- "The Prolift+M was eventually developed by Ethicon in order to continue innovation, continue to maintain efficacy and durability." *Id.* at 7.
- "Overall the design of the Posterior Prolift and Prolift+M not only made sense but it was consistent with the decades-long march towards optimizing correction of prolapse." *Id.*
- "Pelvic floor surgeons were the target audience of this [FDA] notification and would have been expected to read and consider the notice." *Id.*

Ethicon addresses each in turn.

Plaintiff's first challenged statement is presented out of context. The preceding paragraph describes the historical underpinnings of using mesh in pelvic floor repairs. *See* Drolet Report [Dkt. 2093-2] at 14-15. Surgeons – not the medical device industry – initiated the use of synthetic mesh in pelvic floor reconstruction. The published and stated reasons for surgeons making this move toward pelvic mesh was to increase the durability of the repair. Dr. Drolet is describing the published medical literature, which captures the medical judgment of the pioneers of synthetic mesh pelvic floor repair surgeries. She is not attempting to opine on the intent or state of mind of the medical device industry.

The second challenged statement – regarding the development of Prolift+M – does not attempt to opine on the intent of Ethicon. Prolift+M development was part of a linear progression of mesh repair options. Dr. Drolet merely acknowledges that Prolift+M was the next step in that linear progression.

Similarly, the third challenged statement – that Prolift+M made sense and was consistent with the decades-long march towards optimization – is merely recognition of Prolift+M’s place within the linear progression of POP repair devices. Nothing about this statement goes to the intent of Ethicon.

The last statement challenged by Plaintiff concerns the FDA Public Health Advisory. Dr. Drolet says that this advisory was aimed at physicians. This is clear and evident on the faces of the advisories. Dr. Drolet need not attempt to get into the mind of FDA to reach the opinion that these are aimed at physicians. The advisories are documents published by the FDA, for use by physicians, and that form part of the general knowledge of the medical community.

E. Dr. Drolet Does Not Intend To Opine On The Significance Of Obtaining FDA 510(k) Clearance

The only reference to the FDA 510(k) clearance appears on Page 11 of Dr. Drolet’s report wherein she states, “Since that time many modifications of this midurethral sling have been undertaken and in December 2003 Ethicon’s TVT-O received 510-k clearance from the FDA based on the predicated TVT device.” Drolet Report [Dkt. 2093-2] at 11.²

Dr. Drolet does not intend to opine regarding the significance of FDA 510(k) clearance relative to a determination of safety and efficacy. In her deposition, however, Plaintiff asked Dr. Drolet, “If you had seen internal Ethicon documents describing Ethicon’s choices not to perform animal testing prior to marketing the device, would that have been helpful in formulating your

² Ethicon is aware of the Court’s prior rulings regarding the admissibility of evidence of FDA regulatory compliance and does not attempt to reargue its position here.

opinion about whether or not this was a safe and effective device?” Drolet (3/31/16) Dep. Tr. [Dkt. 2093-3] at 87:14-87:20. Dr. Drolet’s answered “[i]t depends.” *Id.* at 87:22. Plaintiff asked Dr. Drolet upon what did it depend, and Dr. Drolet answered “if the FDA cleared [Prolift+M], then it was going to be safe.” *Id.* at 87:24-88:7. Plaintiff then went into follow-up questions regarding the 510(k) clearance process and its relationship to a determination by the agency of safety and efficacy. *See id.* 88:8-89:9. Dr. Drolet answered Plaintiff’s questions. *Id.*

Dr. Drolet does not intend to offer her opinions about the FDA 510(k) clearance process. But she should be permitted to answer fully any questions posed by Plaintiff. Dr. Drolet cannot be faulted for honestly answering Plaintiff’s questions. Plaintiff’s objection to 510(k) opinions should be resolved by Plaintiff avoiding questions that elicit such response from Dr. Drolet.

F. Dr. Drolet’s Opinions Regarding the Adequacy of the IFU Are Reliable

Plaintiff argues that Dr. Drolet cannot opine regarding the adequacy of the IFU because she is “not qualified to act as a regulatory expert” and because her “opinions regarding the adequacy of the IFU are simply made up.” Pls.’ Br. [Dkt. 2094] at 8.

As an initial matter, whether the IFUs adequately advised physicians of the risks associated with the products is not a regulatory opinion. True, there are federal regulations in place that govern the contents and form of an IFU, but Dr. Drolet is not opining as to whether the IFUs satisfied the regulatory requirements.

Similarly, Plaintiff attacks Dr. Drolet because she “never reviewed Ethicon’s internal procedures or documents concerning the contents of an IFU.” *Id.* at 8. Again, Dr. Drolet is not opining as to whether the IFUs met Ethicon’s internal policies.

Dr. Drolet’s opinion is that “the Prolift+M IFU along with the TVT-O IFU which incorporated and was supplemented by professional education and the surgical technique guide,

adequately warned pelvic surgeons . . . of the appropriate risks and complications related to the Prolift & Prolift+M and TVT-O.” Drolet Report [Dkt. 2093-2] at 28. Dr. Drolet’s opinion in this regard is well grounded in both her clinical experience using TVT-O, Prolift+M, and other medical devices and her review of the relevant medical literature. Plaintiff’s argument – that Dr. Drolet’s opinions are inadmissible because she did not rely on FDA regulations or internal Ethicon protocols – rests entirely on the supposition that expertise in FDA regulations related to requirements for IFUs is mandatory for these opinions.

Yet, the job of an expert witness is to provide the facts to which the court can apply the law. It is not the expert’s job to provide the court with the law. This Court, in fact, has excluded testimony which not only stated facts but also expressed a legal conclusion. *In re Ethicon, Inc. Pelvic Repair Systems Product Liability Litigation (Lewis)*, 2014 WL 186872 (S.D. W. Va. 2014) at *20 (citing *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006)). The important question here is whether Dr. Drolet’s testimony is consistent with the law to be applied to the case, and not whether she herself could articulate the governing legal standard. If she had attempted to do that, her testimony would have been excluded.

This Court’s prior decision with regard to one of Ethicon’s expert’s testimony on product warnings was concerned with testimony from an expert that, because she had not experienced certain risks in her clinical practice, then her opinion that such risks need not be contained in the IFU was improper. *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Memorandum Opinion and Order (*Daubert* Motions), Doc. 265 at 35 (S.D. W. Va. Nov. 20, 2014). That is not what Dr. Drolet does here. Nor does she testify that, based upon the risks and complications she has seen in her clinical practice, “there are no other possible risks or complications that should have been included.” *Mathison v. Boston Scientific*, 2015 WL 2124991, at *27 (S. D. W. Va. May 6,

2015). Instead, her warning opinion and opinion that the IFUs are adequate is tied to the knowledge of pelvic floor surgeons based on their education and experience from performing pelvic surgery. Thus, the circumstances here are different from those in *Bellew*, and Dr. Drolet's opinions here are proper. *See Trevino v. Boston Sci. Corp.*, 2016 WL 1718836, *8 (April 28, 2016) at *4 (different circumstances may justify a different ruling when *Daubert* challenges are made).

Dr. Drolet's IFU opinions and qualifications to offer those IFU opinions are similar to those previously found to be admissible by this Court. In *Trevino v. Boston Scientific Corp.*, Civ. A. No. 2:13-cv-01617, 2016 U.S. Dist. LEXIS 56538 (S.D. W. Va. Apr. 28, 2016), the defendant sought to exclude the warnings testimony of plaintiff's urogynecologist Bobby L. Shull, M.D. There, the defendant argued that Dr. Shull as not qualified to opine on the adequacy of the IFU because Dr. Shull "is not an expert in the regulations or standards that govern [IFUs]; he has never advised a company on a DFU; he is unfamiliar with the industry process governing [IFUs]; and he has not even performed a literature search relating to DFUs." *Id.* at * 40. The plaintiff noted that Dr. Shull had not been designated to offer any opinions regarding the manner by which the defendant developed the IFU or the regulatory requirements applicable to IFUs. *Id.* Instead, Dr. Shull was only offered "to opine on the completeness and accuracy of the [product's] warnings from a clinical perspective." *Id.* at *40-41. This Court held that Dr. Shull's testimony along these lines would be admissible:

Dr. Shull will testify about the risks he perceives that the Uphold poses to patients, and he will opine that the [product's IFU] did not convey these risks to physicians. A urogynecologist like Dr. Shull is qualified to make this comparison. *See, e.g., Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 2014 WL 3362264, at *34 (S.D. W. Va. 2014) (finding Dr. Blaivas, a urologist, qualified to testify about the risks of implanting a product and whether those risks were adequately expressed on the product's DFU); *In re Yasmin & YAZ*

(*Drospirenone Prods. Liab. Litig.*, No. 3:09-md-02100, 2011 U.S. Dist. LEXIS 145522, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011) (“[D]octors are ‘fully qualified to opine on the medical facts and science regarding the risks and benefits of [drugs] . . . and to compare that knowledge with what was provided in the text of labeling and warnings’” (quoting *In re Diet Drugs Prods. Liab. Litig.*, MDL 1203, 2000 U.S. Dist. LEXIS 9037, 2000 WL 876900, at 11 (E.D. Pa. June 20, 2000))). I also find that Dr. Shull’s forty years of experience, along with his evaluation of medical literature¹⁰ forms a reliable basis for this testimony. *Kumho Tire Co.*, 526 U.S. at 156 (stating that “an expert might draw a conclusion from a set of observations based on extensive and specialized experience”).

Id. at *41. Just like Dr. Shull, Dr. Drolet is offering her opinion as to the adequacy of the warning based upon her years of clinical experience and her review of the medical literature.

The legal principle that controls here is that a device manufacturer’s duty to warn of adverse events is limited to events unique to the device. It does not include a duty to warn of risks commonly known to the surgeons who use the device. As stated generally in the RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY §2, cmt. j, a product seller “is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users.” *See also* RESTATEMENT (SECOND) OF THE LAW OF TORTS §§388(b), 402A, cmt. j; *Roney v. Gencorp*, 654 F. Supp. 2d 501 (S.D. W. Va. 2009)(adopting “sophisticated user” defense in §388).

This limitation on the duty to warn is recognized in medical cases as well. There is no duty to warn of risks that implanting surgeons commonly know. *See Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers “not well known to the medical community”). In fact, the FDA regulations recognize that that information may be omitted from labeling “if, but only if, the article is a device for which directions, hazards, warnings and other information are *commonly known* to practitioners licensed by law to use the device.” 21 C.F.R. §801.109(c)(emphasis added).

Likewise and as discussed above, under the Pennsylvania learned intermediary doctrine, the question of adequacy of warning is whether a physician, who is under the duty to know the characteristics of the medical device, is adequately apprised of the risks associated with the product in the light of “the data supplied to him from the manufacturer, other medical literature, and any other sources available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug.” *Rowland*, 34 F. Supp. 3d at 570 (quoting *Daniel*, 15 A.3d at 924).

The device IFUs restrict the class of surgeons who are to use the devices. They contemplate that users will be familiar with traditional surgical techniques used to treat stress urinary incontinence. *See* Ex. A, TVT-O IFU at 1 (ETH.MESH.00860240) (“This package insert is designed to provide instruction for use of the GYNECARE TVT* Obturator System It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence). The device should be used only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the GYNECARE TVT Obturator device. These instructions are intended for general use of the device.”); Ex. B, Prolift+M IFU (ETH.MESH.01595615) at 2 (“Physicians should have experience in management of complications resulting from procedures using surgical mesh. . . . Users should be familiar with surgical procedures and techniques involving pelvic floor repair and synthetic meshes before employing the GYNECARE PROLIFT+M™ Systems.”).

So the important question with respect to Plaintiff’s failure to warn claim is what “hazards” and are “commonly known” to surgeons familiar with pelvic surgery, including surgery to address pelvic organ prolapse and SUI. That is precisely the opinion reached by Dr. Drolet. Given the state of medical knowledge, the IFUs adequately apprised surgeons of the risks

associated with the products. Ethicon had no duty to warn of adverse events “commonly known” to those surgeons. Its duty was to warn of adverse events that were unique to the mesh devices. If Plaintiff intends to argue at trial that Ethicon’s IFU failed to disclose certain risks, Ethicon is fully entitled to defend such claims by demonstrating that those risks were obvious to the users of the product (pelvic surgeons), and therefore, did not need to be disclosed.

G. Dr. Drolet Does Not Offer Any Legal Conclusions

Plaintiffs point to only one alleged “legal conclusion” offered by Dr. Drolet – that the IFUs “adequately warned pelvic surgeons.” Pls.’ Br. [Dkt. 2094] at 9. This is not a legal conclusion, this is a factual opinion. While this opinion does “embrace an ultimate issue” that the jury must decide, it is not objectionable just because it does so. *See* Fed. R. Evid. 704.

As this Court recently noted, experts should not be allowed to “state[] a legal standard,” “draw[] a legal conclusion by applying the law to the facts” of the case, or “using legal terms of art, such as ‘defective,’ ‘unreasonably dangerous,’ or ‘proximate cause.’” *Trevino v. Boston Scientific Corp.*, 2016 U.S. Dist. LEXIS 56538, at * 7-8 (S.D. W. Va. Apr. 28, 2016). Dr. Drolet attempts none of these things. Rather, she opines that, as a physician experienced in the implantation of pelvic floor devices, Ethicon sufficiently apprised her and other reasonably prudent physicians of the risks associated with the products. Whether these warnings were sufficient to render the products non-defective or not unreasonably dangerous (i.e., the ultimate legal conclusions) remain questions within the sole province of the jury.

H. Dr. Drolet Sufficiently Identified The Materials Upon Which She Relied

In conjunction with her report, Dr. Drolet supplied a list of all documents made available to her and upon which she relied when arriving at her opinions. During her deposition, Plaintiff questioned Dr. Drolet regarding whether she read certain documents contained on that listing

and, if so, what role those documents played in her opinion. Dr. Drolet testified that she did not recall reading certain of the documents contained on the list. Plaintiff contends – without any citation to a legal authority – that somehow this renders her testimony inadmissible.

Dr. Drolet sufficiently identified the documents upon which she relied. In fact, her 49-page Report is replete with citations to the articles, studies, RCTs, meta-analysis, position papers, and other documents upon which she relied. That Dr. Drolet had in her possession more documents than those cited in her expert report is not a basis for excluding her testimony.

Again, if Plaintiff believes there is information in these other documents – both those Dr. Drolet possessed and those she did not possess – that contradict her opinions, Plaintiff can attempt to cross-examine her with those documents. But not reading or not recalling having read a document does not render Dr. Drolet's opinion testimony unreliable.

Similarly, Plaintiff complains that Dr. Drolet was not provided with certain depositions of current and former Ethicon employees. Again, this is a point for cross-examination, not *Daubert*.

Lastly, Plaintiff contends that Dr. Drolet testified that “these materials might alter her expert opinions about the Prolift device.” Pls.'s Br. [Dkt. 2094] at 11. Nowhere does Plaintiff cite anything to support this assertion. Dr. Drolet has not testified that the contents of the Ethicon employee depositions “might alter her expert opinions.” That assertion is pure speculation on Plaintiffs' part.

II. CONCLUSION

For the above reasons, Ethicon and Johnson & Johnson respectfully request that this Court enter an order denying Plaintiff's Motion to Exclude Certain Testimony of Julie Drolet, M.D. [Dkt. 2093].

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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/s/Christy D. Jones